National Grain and Feed Association

1250 Eye St., N.W., Suite 1003, Washington, D.C. 20005-3922, Phone: (202) 289-0873, FAX: (202) 289-5388, Web Site: www.ngfa.org

September 14, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 2003N-0312 – Animal Feed Safety System

The National Grain and Feed Association submits this statement in response to the Food and Drug Administration's request for comments regarding the agency's draft documents pertaining to its intention to pursue an Animal Feed Safety System initiative.

The NGFA, established in 1896, consists of 1,000 grain, feed, processing, exporting and other grain-related companies that operate about 5,000 facilities that handle more than two-thirds of all U.S. grains and oilseeds. With more than 300 member companies operating feed manufacturing and integrated livestock and poultry operations, the NGFA is the nation's largest trade association representing commercial feed manufacturer and integrator interests.

The NGFA's membership encompasses all sectors of the industry, including country, terminal and export elevators; feed mills; cash grain and feed merchants; end users of grain and grain products, including processors, flour millers, and livestock and poultry integrators; commodity futures brokers and commission merchants; and allied industries, such as railroads, barge lines, banks, grain exchanges, insurance companies, computer software firms, and engineering and design/construct companies. The NGFA also consists of 35 affiliated state and regional U.S. grain and feed associations, as well as two international affiliated associations. The NGFA has strategic alliances with the Grain Elevator and Processing Society and the Pet Food Institute, and a joint operating and services agreement with the North American Export Grain Association.

Specifically, this statement provides the NGFA's views on two draft documents issued by FDA concerning its Animal Feed Safety System: 1) draft definitions of "comprehensive" and "risk-based;" and 2) draft elements of an Animal Feed Safety System.

The NGFA previously submitted a statement, dated Nov. 5, 2003, in which it commended FDA for exploring the development of a comprehensive, risk-based approach to food and feed safety. The NGFA also was an active participant in the September 23-24 FDA public meeting at which the agency launched the Animal Feed Safety System initiative. NGFA Feed Legislative and Regulatory Affairs Committee Chairman Joe Garber of Wenger's Feed Mill Inc. provided a feed industry perspective on quality-control systems, and 10 members representing NGFA's Animal Agriculture Committee, Feed Legislative and Regulatory Affairs Committee, and Feed Manufacturing and Technology Committee, as well as staff members, participated in the various breakout sessions and general sessions of the meeting.

We believe the forum resulted in a constructive exchange of views by a significant cross section of the commercial feed ingredient, rendering, feed manufacturing and pet food sectors, federal and state government officials, academicians, and consumer interests, although we wish that more representation had been present from the producer/on-farm and transportation sectors. We believe the public meeting succeeded in giving participants an opportunity to begin framing the myriad and complex issues involved in considering a comprehensive, risk-based approach to animal feed safety.

From a "macro" perspective, we're certain FDA appreciates the enormity of the task on which it is embarking. While it is prudent for FDA to change its approach toward a comprehensive and risk-based approach, the NGFA believes it is essential that when doing so the agency recognize that regulations and regular inspections already are in place for the commercial medicated feed manufacturing sector. So that FDA can "wrap its arms around" this initiative, it also will be important for the agency to identify and examine the effectiveness of feed safety initiatives already being pursued by the private sector.

The NGFA believes it is useful for FDA to develop definitions for "comprehensive" and "risk-based," as well as to identify potential elements of an Animal Feed Safety System. Doing so will provide a framework and a common set of principles on which to develop the specific components of such a system. We also believe it will help identify and provide an opportunity to resolve potential inconsistencies or paradoxes, some of which the NGFA addresses subsequently in this statement.

The NGFA offers the following specific recommendations concerning the draft definitions and elements of an Animal Feed Safety System.

Draft Definition of "Comprehensive"

The NGFA strongly supports FDA's intention to embrace a much more comprehensive approach that is inclusive of <u>all sectors</u> of the animal feed and feed ingredient industry. FDA has promulgated a comprehensive set of current good manufacturing practice regulations (cGMPs) for both licensed and non-licensed medicated feed manufacturers, which establish a recognized feed regulatory compliance

bar for the production and distribution of medicated feeds. In practice, those regulations have been applied and enforced predominantly – if not almost exclusively – on the commercial feed manufacturer, even though such establishments represent only a fraction of the feed and feed ingredient tonnage produced in the United States. Several incidents of concern involving various hazards and contaminants (e.g., dioxin, microbial concerns, mycotoxins, pesticides and unsafe substances in transport conveyances) have reinforced the importance of FDA adopting a more inclusive approach to feed safety that recognizes the industry's multiple sectors and their respective diversities. **Thus, the NGFA believes a priority should be placed on addressing those industry sectors for which cGMPs and oversight inspections currently do not exist.**

The following comments address the eight concepts identified by FDA in its draft definition of "comprehensive."

1. *"It would apply to the whole range of feed products, including all ingredients and finished feeds."*

   The NGFA strongly supports FDA's intent to use the Animal Feed Safety System initiative to address, in a risk-based way, the safety of a full range of feed products – from feed ingredients to final feed products.

2. *"Use ingredients approved and/or recognized by an established regulatory agency or entity whose members are charged with a responsibility of enforcing laws regulating the production, labeling, distribution, or sale of animal feeds."*

   The NGFA strongly supports this concept. But we do suggest adding the phrase *"…that are generally recognized as safe"* to reference GRAS and GRAS self-affirmation into this concept. Specifically, the NGFA suggests that this concept be modified to read: *"Use ingredients that are approved**, generally recognized as safe,** and/or recognized by an established regulatory agency or entity…." [New language boldfaced and underscored.]*

   Concerning this issue, the NGFA has expressed repeated concerns over the proliferation of so-called "novel" ingredients that are not generally recognized as safe for their intended use, have not been defined under the Association of American Feed Control Officials' ingredient definitions process, nor been approved by FDA. The NGFA hopes FDA and state and provincial feed control officials will take the opportunity provided by this Animal Feed Safety System initiative to enforce existing feed rules and not permit the continued feeding of non-approved additives.

3. *"Cover the complete range and variety of facilities involved in animal feed production."*

   The NGFA strongly supports the concept that all establishments **and**

conveyances be encompassed by an Animal Feed Safety System. Missing from FDA's draft language is the transportation component, where the potential for contamination of feed and feed ingredients is a significant concern of commercial feed manufacturers. As such, the NGFA suggests that this concept be rewritten as follows: *"Cover the complete range and variety of facilities**, equipment and conveyances** involved in ~~animal feed production~~ **the manufacture and distribution of animal feed and feed ingredients**."* *[New language boldfaced and underscored; deleted language stricken through.]* The NGFA also suggests renumbering the eight concepts and placing this as the first item.

As noted previously, to date the regulatory and inspection focus of FDA and states has been on commercial feed mills manufacturing medicated feeds. The Animal Feed Safety System initiative provides FDA with an opportunity to engage other industry sectors, including ingredient suppliers and on-farm mixer-feeders, in minimizing hazards that may be associated with their respective sectors. The NGFA believes it would be appropriate for FDA to tailor animal feed safety initiatives to the specific sector, type of operation, and type of feed and/or feed ingredients manufactured and distributed; a one-size-fits-all approach will not be effective.

4. *"Have the flexibility to be process- or product-oriented, depending on the situation."*

The NGFA reads this statement as FDA's intent to devise an Animal Feed Safety System that provides the flexibility for different sectors of this broad and diverse industry to adopt those quality-assurance methods that are most appropriate, relevant and effective for their respective sector. Currently, as noted previously, the commercial medicated feed manufacturing sector is the only industry segment with mandatory cGMP regulations, and licensed commercial medicated feed mills are the only segment with mandatory routine inspections – save those conducted of various establishments for compliance with FDA's BSE-prevention feed rule. **For the commercial feed manufacturing sector, the NGFA strongly supports these cGMP-type regulatory approaches.**

Some commercial feed mills also voluntarily have chosen – or may choose – to include hazard analysis and critical control point (HACCP or HACCP-like) **principles** (not government-mandated standards) as part of their quality-assurance and cGMP-based programs. But it is important to stress that many feed industry sector participants likely will conclude, after thoroughly analyzing their own quality-control and cGMP-based programs, that HACCP principles are inappropriate for their type of business or operation, or are not their preferred quality-assurance approach. As such, the NGFA urges FDA **not** to develop HACCP standards as part of its AFSS initiative. At best, as stated by the NGFA in its Nov. 5, 2003 statement to FDA, there may be an

appropriate role for the agency in developing basic guidelines or principles concerning the elements or components that should be addressed by establishments that voluntarily choose to adopt one or more of the proliferating types of quality-assurance methods (such as HACCP, HACCP-like, ISO, etc.) **as a means of enhancing the level of understanding about what each method does – and doesn't – encompass.** To reiterate, however, it is important that the agency **not** attempt to develop a "model HACCP standard."

5. *"Address feeds produced for food and non-food animals."*

   The NGFA believes that feed and feed ingredients should be safe regardless of whether they are intended for food- or non-food-producing animals. We also recognize that FDA's statutory mandate under the Federal Food, Drug and Cosmetic Act makes the agency responsible for addressing feed safety for both food- and non-food-producing animals. However, while we do **not** suggest a change to the terminology used by FDA in depicting this concept, the NGFA believes it is appropriate for FDA, given limited resources, to focus first on feed safety issues relevant to food-producing animals that pose risks to human health, rather than on feed safety for non-food-producing animals. With respect to non-food-producing animals, it is important for FDA to recognize that existing tort laws and product liability obligations impose effective marketplace disciplines that contribute to feed safety, as do existing private sector quality-assurance programs.

6. *"Cover all known hazards, and be applicable to hazards not yet identified."*

   The NGFA has several comments on the wording of this concept. First, this is an instance where we believe FDA's depiction of "comprehensive" conflicts with its philosophy of utilizing a "risk-based" approach. Not all "known hazards" are harmful to human and/or animal health. And the quality-control measures needed to address hazards so they are not harmful can vary dramatically, depending upon the hazard. Second, we believe it is important for FDA to instill in this section the concept that hazards be identified through scientific risk assessment. Third, the NGFA is concerned about FDA's reference to "hazards not yet identified," since we believe the Animal Feed Safety System should address only known – not "hypothetical" or "potential" – hazards. We surmise that FDA's intent in referencing "hazards not yet identified" is to structure the Animal Feed Safety System in such a way as to be flexible and adaptable to known hazards, regardless of whether those risks are identifiable now or in the future. We believe this inference, as well as NGFA's three concerns, can be addressed by revising the wording of this concept to read: *"~~Cover~~ **Be adaptable to address** all known hazards **determined through scientific risk-assessment, now or in the future, to be harmful to human and/or animal health**. ~~and be applicable to hazards not~~*

~~yet identified~~." [New language boldfaced and underscored; deleted language stricken through.]

7. *"Address both human and animal health issues."*

   Again, while we do not object to the phraseology used by FDA, the NGFA believes that FDA should place a priority on addressing safety-related issues associated with feed or feed ingredients intended for food-producing animals, particularly those that are shown through risk-based analyses to pose a danger to human health.

8. *"Acknowledge and coordinate regulatory authorities at all levels, including local, state, tribal and federal, involved in feed safety."*

   The NGFA strongly supports government-based inspections and oversight. As such, the NGFA supports enhanced partnership, coordination and interaction between FDA and other governmental regulatory authorities. State and provincial feed control agencies, in particular, play a key role in providing government-based oversight to address animal feed safety matters.

   In this regard, the NGFA also strongly encourages FDA to incorporate the principles contained in the so-called "Voluntary Self-Inspection Program" (VSIP) into its Animal Feed Safety System initiative. We also believe FDA should use this opportunity to broaden VSIP to encompass both medicated and non-medicated feed and feed ingredients. Doing so would provide an important additional incentive to encourage the adoption of quality-assurance principles by the private sector, while enabling government to more effectively target its scarce inspection, compliance and enforcement resources.

   Under the VSIP approach, developed through the Association of American Feed Control Officials with active input and support from the NGFA, establishments would be encouraged to develop and implement quality-assurance programs that meet federal standards or guidelines. Among other things, VSIP includes the following concepts: 1) Establishments would enter into a binding agreement with FDA committing to develop and implement a written Q/A program that meets FDA standards or guidelines; 2) participating establishments would conduct annual self-inspections of their operations and correct deficiencies; 3) participating establishments would submit summary results of their inspections to FDA and state feed control authorities; and 4) participating establishments would be subject to random spot-check audits by government to ensure the quality-assurance programs are being implemented. In return, participating establishments would be a low priority for federal (and the NGFA submits should be for state) inspections, except for cause.

The NGFA believes there is a need for FDA to address two other concepts omitted from its current draft definition of "comprehensive."

- First, FDA should commit, as part of a comprehensive approach, to conducting the research necessary to base actions associated with the Animal Feed Safety System on sound scientific principles. One of the disturbing undercurrents at FDA's September 2003 public meeting was a misperception – in our view – that the research on which to conduct risk assessment under a prudent animal feed safety system already had been completed. We believe that is an erroneous assumption.

- Second, FDA should commit to facilitating access to rapid, inexpensive and reliable diagnostic tests (such as quick tests and assays) that yield accurate and consistently repeatable results for use by affected industry sectors to monitor and detect feed safety hazards (e.g., pathogens, dioxins, pesticides, mycotoxins, etc.) that may be identified through science-based risk assessment.

For these reasons, the NGFA recommends that FDA consider incorporating the following two concepts, which we suggest be sequentially numbered as shown so that they flow with the rest of the enumerated items:

7. ***"Commit to conducting additional research, when necessary, to ensure that hazard determinations are made based upon sound and accurate scientific principles."***

8. ***"Commit to facilitating access to rapid, inexpensive and reliable diagnostic tests that yield accurate and consistently repeatable results to monitor and detect feed safety hazards that may be identified through science-based risk assessment."***

Draft Definition of "Risk-Based"

The NGFA commends FDA for grounding its Animal Feed Safety System in a risk-based approach. However, we believe it is important to include in FDA's draft definition of "risk-based" two concepts that currently are absent.

- First, we believe the definition should make reference to utilizing the best-available science when conducting risk assessment.

- Second, we believe the agency should make reference to non-regulatory approaches in FDA's tool box that may be the most effective means for addressing certain feed safety issues. These tools may include, but not be limited to, agency guidance; education and information; and perhaps public- and private-sector quality assurance initiatives.

Thus, the NGFA suggests revising the draft definition of "risk-based" as follows:

"A risk-based approach for the Animal Feed Safety System identifies and assesses, ***based upon the best-available science,*** *the risks to animal and human health posed by biological, chemical and physical hazards in animal feed. In this context, risk is a function of the likelihood of human or animal exposure to deleterious amounts of such hazards in feeds, and the significance of the health consequences in response to those exposures. Analysis of the risks posed by feed hazards will help the agency identify the* ***most*** *appropriate* ***and effective*** ~~*regulatory*~~ *approach for each hazard,* ***which may include regulation, guidance, education/information and/or public/private-sector initiatives,*** ~~*and will*~~ ***thereby*** *permit****ting*** *the agency to make effective and efficient use of* ~~*regulatory*~~ *resources." [New language boldfaced and underscored; deleted language stricken through.]*

Elements of an Animal Feed Safety System

The NGFA supports the intent of FDA's draft introductory paragraph to its basic elements applicable to any Animal Feed Safety System, which correctly in our view states that the elements should be incorporated into the standard operating procedures of any feed or feed ingredient manufacturer, distributor, transporter or user.

The NGFA does suggest some minor rewording so that this initial paragraph reads as follows:

"The following bullets are some basic elements of any animal feed safety system. Every feed and/or feed ingredient ***manufacturer,*** ~~*transporter*~~*, processor, distributor****, transporter*** *and user should be incorporating these elements,* ***as appropriate,*** *into their* ~~*animal feed business process*~~ ***standard operating procedures****. The detail and extent to which any of these elements apply to a specific product or line of products will depend upon the product itself, its use, the facility structure and equipment,* ~~*and*~~*the distribution and feeding mechanism,* ***and the size and type of operation, including its staffing/work force levels****."*

The NGFA offers the following specific recommendations concerning FDA's enumerated draft basic elements:

"*1. Incoming materials-know what you are getting. (a. through f.)"*

The NGFA believes FDA should reword and refocus this element to address the responsibility of suppliers to ensure the safety of ingredients provided to the feed and feeding sectors. As currently written, this element is focused exclusively on the receiver (e.g., feed manufacturer or feeder). While the NGFA believes the items addressed by FDA generally are relevant, they will vary in scope and detail based upon the type of inbound material being received and the type and size of industry segment involved. For instance, the NGFA believes FDA's current cGMPs *[21 CFR 225]* adequately address these components for the commercial medicated feed manufacturing sector.

The NGFA offers the following suggested changes to the terminology used by FDA for this element *[new language boldfaced and underscored; deleted language stricken through.]* Explanatory notes, if warranted, are inserted alongside the recommended changes:

"1. ***Supplies of feed ingredients and other*** ~~*Incoming*~~ *materials* ***used in feed*** ***-*** ~~*know what you are getting*~~*"*

> *"****a. Establish and periodically review quality specifications and controls used in the manufacture of feed ingredients to ensure products are safe and acceptable for the intended specie(s).****"*
>
> [Explanatory Note: This terminology is intended to incorporate the responsibility of the feed ingredient supplier to monitor and control feed ingredient safety.]
>
> *"****b. Verify the*** ~~*Assure*~~ *identity of material.* ***Have suppliers certified that ingredients meet certain safety and quality standards established for the type of ingredient product(s)?*** *If Certificates of Analysis [COAs]* ***attesting to the composition of feed or feed ingredients*** *are used* ***by suppliers****, consider* ***conducting*** *periodic audits of suppliers of COAs."*
>
> [Explanatory Note: These suggestions are intended to include the responsibility of suppliers to verify the safety standards applicable to their respective ingredients, as well as to amplify the purpose of COAs.]
>
> *"****c.*** *Is the material susceptible to* ~~*any*~~ *contamination* ***at levels that pose a risk given the species for which the feed or feed ingredients may be used****? Do you need additional assurance****,*** *such as testing****?****"*
>
> [Explanatory Note: These suggestions reflect a risk-based approach to contaminants – they should be of concern if they are present at levels that may be unsafe to the species for which the feed/feed ingredients are intended.]
>
> *"****d.*** *Receiving procedures –* ***sampling;*** *control measures [when does it occur, who does it, is the equipment dedicated];* ***and*** *clean-out* ***procedures [if necessary to avoid cross-contamination]****."*
>
> [Explanatory Note: The NGFA believes that obtaining representative samples is an important quality-assurance step, and already are addressed in cGMPs applicable to commercial medicated feed manufacturers.]
>
> *"****e.*** *Storage – labeled* ~~*bins,*~~ */designated bins; clean-out between receipt of different shipments* ***[when necessary to avoid contamination];*** ~~*what else is stored with or near*~~ ***avoid accidental contamination of feed/feed ingredients with toxic or other non-feed*** *materials."*

[Explanatory Note: This language is intended to clarify proper storage and equipment clean-out procedures; again, these are reflected in cGMPs applicable to medicated feed.]

*"**f.** Inventory and periodic accountability."*

[NGFA Comment: The NGFA believes FDA needs to clarify this element, particularly concerning the type(s) of products for which it "inventory" and "periodic accountability" are appropriate **from the standpoint of a risk-based feed safety system**. For instance, the NGFA believes it is appropriate – as required under the current medicated feed cGMPs, that receipt-and-use records be required for certain animal drug products used in the manufacture of feed. But the same "inventory" and "periodic accountability" – from a **feed safety standpoint** would not be appropriate for, say corn or soybean meal inventories (although it would merit attention from **non-feed-safety**, private sector loss-control standpoint.]

*"**g.** Written SOPs, **depending upon the type, size, complexity of the operation or the number of personnel involved.**"*

[Explanatory Note: The NGFA believes that written SOPs are advisable in most cases, but may be inappropriate for extremely small commercial or on-farm establishments where one or two persons are responsible for the manufacture and/or feeding of products.]

"2. Processing/Manufacture"

For commercial medicated feed establishments, the requirements listed by FDA in this section already have been implemented through the agency's cGMP regulations. The NGFA believes they are appropriate considerations for other sectors, as well.

The NGFA offers the following suggested editorial changes *[new language boldfaced and underscored; deleted language stricken through.]*:

*"a. What are critical steps to the process? **Are the correct formulas and mixing instructions available?** Are the mix times adequate? Are there other time and/or temperature/pressure requirements? Do you need in-line specifications? Do you need production schedules? Are there cross-contamination possibilities that need to be controlled? Is this a simple mix operation or are there special processes, such as pelleting?"*

*"b. Equipment maintenance - ~~w~~**W**hat equipment is needed? Is it in working order? **Is the equipment, including scales and other measuring devices, capable of producing safe feeds and/or feed ingredients?** Are there QC checks that should be done on the equipment; how and how often? Is equipment specified for particular production runs or products? **When are***

***c**lean-out procedures warranted to avoid cross-contamination?* What are the**ose** clean-out steps and when it clean-out done?"*

*"c. Product Labeling - labels on file; who prepares labels**?**; how are labels verified**?**; are checks needed to assure the correct label is on the **correct** product**?**"*

*"d. Written SOPs, **depending upon the type, size, complexity of the operation or the number of personnel involved.**"*

[Explanatory Note: Again, the NGFA believes that written SOPs are advisable in most cases, but may not be appropriate for extremely small commercial or on-farm establishments where one or two persons are responsible for the manufacture and/or feeding of products.]

"3. Record Keeping"

These requirements are consistent with current medicated feed cGMPs, and the NGFA fully supports their relevance and continued application for commercial feed establishments. The NGFA believes these requirements should be extended to the other feed industry segments, where appropriate.

*"a. **Maintain** ~~R~~records of **steps** important ~~steps~~ **to feed/feed ingredient product safety that occur in the** receipt, production, distribution, **transport and use of feed and feed ingredients** ~~maintained~~."*

*"b. Specify the minimum records and the information in each record [~~take from~~ **FDA's** BSE**-prevention regulations and medicated feed c**GMPs **provide useful models.** ~~etc.~~]"*

*"c. Written SOPs, **depending upon the type, size, complexity of the operation or the number of personnel involved.**"*

[Explanatory Note: Again, the NGFA believes that written SOPs are advisable in most cases, but may be inappropriate for extremely small commercial or on-farm establishments where one or two persons are responsible for the manufacture and/or feeding of products.]

"4. Distribution/Transportation/Feeding"

The NGFA conceptually agrees with the elements included by FDA in this section, although they appear to be written in a way that applies primarily to commercial feed establishments. We have suggested rewording or expanding on several of these elements to make them more universally relevant to all sectors. *[New language boldfaced and underscored; deleted language stricken through.]*

"a. ***Verify the delivery destination for feed/feed ingredients.*** *Know who, what, when, where, and* ~~*how much*~~ ***the quantity of feed materials to be delivered*** ~~*for distribution of material.*~~ ***Ensure that feed and feed ingredients are accompanied by required label information, including feeding directions.*** ~~*Distribution should include feeding of product to food-producing animals.*~~*"*

[Explanatory Note: We believe these changes more accurately reflect FDA's intent.]

"b. How is material transported? ***Can shippers/transporters accurately identify the type of product transported in the previous load hauled in the conveyance, and document whether and how the conveyance was cleaned out between loads to avoid potential cross-contamination?*** *Are special precautions needed?* ~~*What was transported previously?*~~ ~~*Do you need to have clean-out between transport?*~~*"*

"c. ~~*Procedures for identifying and controlling product that is not sold, used, or fed.*~~ ***Are records maintained or other procedures implemented to identify all feed/feed ingredients shipped, received and used, as well as the disposition of unused feed/feed ingredients?****"*

[Explanatory Note: We believe these changes more accurately reflect FDA's intent.]

"d. Procedures to ~~*get product back*~~ ***retrieve and recover products*** *from marketplace if* ~~*needed*~~ ***they subsequently are found to pose a feed safety risk*** *[recall]."*

"e. Written SOPs, ***depending upon the type, size, complexity of the operation or the number of personnel involved.****"*

[Explanatory Note: Again, the NGFA believes that written SOPs are advisable in most cases, but may be inappropriate for extremely small commercial or on-farm establishments where one or two persons are responsible for the manufacture and/or feeding of products.]

"5. Inspection/Audit/Corrective Action"

Again, while we agree conceptually with the elements contained in this section, they are written in a way (e.g., complaint files, etc.) that appears to be targeted on the sector of the industry already regulated under medicated feed cGMPs – commercial feed mills. The NGFA suggests the following changes *[new language boldfaced and underscored; deleted language stricken through.]*:

"a. Establish procedures to periodically conduct ~~*internal*~~ ***self-****inspection and audit****s*** *of* ***quality-****control systems* ~~*and test results*~~ *- Are SOPs being followed?*

Are internal specifications being met? Are labels current and accurate? Were deviations ***(e.g., between theoretical versus actual use of ingredients; yields of feed production; feed use on-farm, etc.)*** *investigated* ***and reconciled****?"*

"b. ~~*Maintain a complaint file and review, evaluate*~~*,* ***Are feed/feed ingredient quality or safety issues addressed*** *and* ~~*implement*~~ *corrective action* ***implemented*** *when problems are identified? Do you need to provide notification of a corrective action [such as recall] to a regulatory agency?"*

"c. *Written SOPs,* ***depending upon the type, size, complexity of the operation or the number of personnel involved.****"*

[Explanatory Note: Again, the NGFA believes that written SOPs are advisable in most cases, but may be inappropriate for extremely small commercial or on-farm establishments where one or two persons are responsible for the manufacture and/or feeding of products.]

"6. ***Training and*** *Responsibilities"*

The NGFA recommends that sections 6 and 7 be combined into a single section, entitled "Training and Responsibilities." Further, the NGFA believes both of these sections are written from the standpoint of a commercial feed manufacturer, not from the standpoint of ingredient suppliers, transporters, on-farm mixer-feeders and other non-commercial establishments involved in the feed chain. For these reasons, the NGFA suggests the following changes *[new language boldfaced and underscored; deleted language stricken through.]*

"a. Determine responsible individuals for controls and corrective action throughout the receipt, processing, ***transport*** *and distribution****, feeding, and marketing of feed/feed ingredients and food-producing animals.****"*

~~*"b. Establish criteria that assures the individuals are trained and understand their responsibilities.*~~

~~*"7. Training"*~~

*"****b.*** *Provide training to employees on regular basis - level and extent of training and oversight will depend on product and product ingredients* ***being received, manufactured, processed, transported and fed,*** *and individual employee responsibilities.*

*"****c.*** *Include* ~~*government requirements in training*~~ ***training in government regulatory requirements, as appropriate to the type of establishment and operation.***

*"****d.*** *Written SOPs,* ***depending upon the type, size, complexity of the operation or the number of personnel involved.****"*

[Explanatory Note: Again, the NGFA believes that written SOPs are advisable in most cases, but may be inappropriate for extremely small commercial or on-farm establishments where one or two persons are responsible for the manufacture and/or feeding of products.]

Conclusion

If grounded in sound science that is based upon solid research **and** if truly comprehensive and risk-based, the NGFA believes that an Animal Feed Safety System has the potential to:

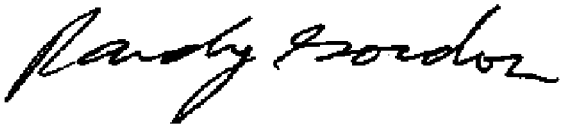
- Establish a baseline and provide a more uniform framework to guide activities of federal and state government, and the feed ingredient, feed manufacturing, transport, and on-farm and commercial mixer-feeder sectors in addressing those hazards most important to preserving and enhancing feed safety. In so doing, such a federal initiative could provide a more level playing field in the market.

- Enable government agencies to better focus scarce human and financial resources on those areas most critical to feed and food safety, while reducing the need to respond to perceived or actual feed safety "emergencies."

- Further enhance consumer confidence in the safety of meat, milk and eggs through education efforts.

The NGFA appreciates FDA's consideration of its views, and looks forward to being a fully engaged and constructive participant in future discussions with the agency and other interested parties on this important matter.

Sincerely yours,



Joseph Garber
Chairman, Feed Legislative
and Regulatory Affairs Committee

Randall C. Gordon
Vice President, Communications
and Government Relations

cc: Dr. Stephen F. Sundlof
Dr. Daniel G. McChesney
Dr. George A. Graber